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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,148

08/17/2006

Jane Louise Holley

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

12/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,148	Applicant(s) HOLLEY ET AL.	
	Examiner Mark Navarro	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment filed September 12, 2008 has been received and entered. Claims 20 and 22 have been cancelled. Accordingly, claims 1-19 and 21 are pending in the instant application, of which claims 19 and 21 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of an antibody which is "IgT" is withdrawn in view of Applicants response.

Claim Rejections - 35 USC § 101

2. The rejection of claims 1-18 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. The rejection of claims 1-18 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Habermann et al is maintained.

Applicants are asserting that Habermann fails to teach a composition containing the combination of an antibody and a **fragment** of an antibody or a composition including the combination of two antibody **fragments**. In addition, Habermann fails to teach a composition having binding agents that bind to the **same** toxin.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants assert that Habermann fails to teach a composition containing the combination of an antibody and a **fragment** of an antibody or a composition including the combination of two antibody **fragments**. However, Applicants are respectfully directed to their own claim language. Claim 1 recites “A pharmaceutical composition **comprising**...” (Empasis added). The transitional phrases “comprising”, “consisting essentially of” and “consisting of” define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) (“like the term comprising,’ the terms containing’ and mixture’ are open-ended.”).< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). Simply stated, the transitional phrase of comprising specifically allows for the presence

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of an entire antibody within the breadth of the claims, since an entire antibody clearly contains fragments of an antibody.

Finally, Applicants assert that Habermann fails to teach a composition having binding agents that bind to the **same** toxin. Applicants arguments appear to be mutually exclusive from Applicants claims. For instance, assuming claim 13 is a proper further limiting claim, it recites "wherein the composition comprises sets of first and second specific binding agents each set of specific agents binding a different one of botulinum toxins A, B, C, D, E, F, or G." Clearly Applicants claims allow for sets of antibodies which bind to botulinum toxin A and B, precisely what is disclosed by Habermann et al. Furthermore, botulinum toxin A and B are both botulinum toxins, thereby meeting the limitation of "same toxin."

The claims are directed to a pharmaceutical composition comprising a first specific binding agent selected from an isolated antibody that specifically binds a target toxin or a large binding fragment of an antibody wherein the large binding fragment specifically binds the target toxin, and a second specific binding agent that comprises a small binding fragment of an antibody wherein the small binding fragment binds the toxin.

Habermann et al (Med. Microbiol. Immunol. Vol. 161, pp 203-210, 1975) disclose of an isolated composition of human antibodies which bind to botulinum toxin A, B, and E. (See abstract). Habermann et al further disclose of administering the composition of antibodies to animals to protect against the sequelae of botulinum toxin

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A and B. Habermann et al further disclose the serum to contain 3.2U anti-A and 2.5U of anti-E.

Given that Habermann et al disclose of pharmaceutical compositions comprising antibodies to botulinum toxin A (first specific binding agent) and botulinum toxin E (second specific binding agent), which are human antibodies, the disclosure of Habermann et al is deemed to anticipate the instantly filed claims.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
December 10, 2008